

Formula I

wherein, as valence permits,

$R_2$ ,  $R_3$ ,  $R_4$ , and  $R_5$ , represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

$R_6$ ,  $R_7$ , and  $R'_7$ , are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ , or

$R_6$  and  $R_7$ , or  $R_7$  and  $R'_7$ , taken together form a ring or polycyclic ring;

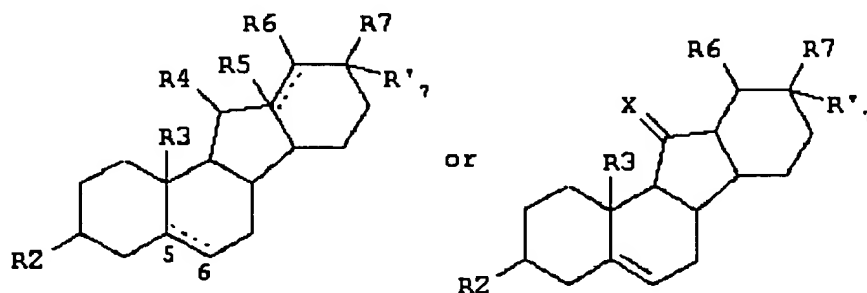
with the proviso that at least one of  $R_6$ ,  $R_7$ , or  $R'_7$  is present and includes a primary or secondary amine;

$R_8$  represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

and

$m$  is an integer in the range 0 to 8 inclusive.

5. (Reiterated) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to a patient a composition comprising a purified steroidal alkaloid represented in the general formula (II), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula II

wherein

$R_2$ ,  $R_3$ ,  $R_4$ , and  $R_5$ , represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

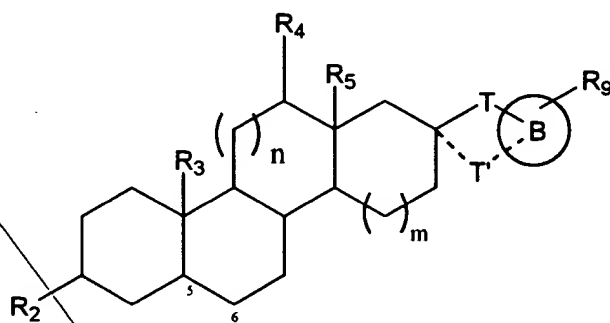
$R_6$ ,  $R_7$ , and  $R'7$ , are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ , or

$R_6$  and  $R_7$ , or  $R_7$  and  $R'7$ , taken together form a ring or polycyclic ring, with the proviso that at least one of  $R_6$ ,  $R_7$ , or  $R'7$  is present and includes a primary or secondary amine;

$R_8$  represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;  
 $m$  is an integer in the range 0 to 8 inclusive; and

$X$  represents O or S.

6. (Amended Twice) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified alkaloid represented in the general formula (III), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula III

wherein

R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>5</sub>, represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH<sub>2</sub>)<sub>m</sub>-R<sub>8</sub>;

R<sub>8</sub> represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

B represents monocyclic or polycyclic groups;

T represents an alkyl, an aminoalkyl, a carboxyl, an ester, an amide, ether or amine linkage of 1-10 bond lengths;

T' is absent, or represents an alkyl, an aminoalkyl, a carboxyl, an ester, an amide, ether or amine linkage of 1-3 bond lengths, wherein if T and T' are present together, than T and T' taken together with the ring B form a covalently closed ring of 5-8 ring atoms;

R<sub>9</sub> represent one or more substitutions to the ring B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers,

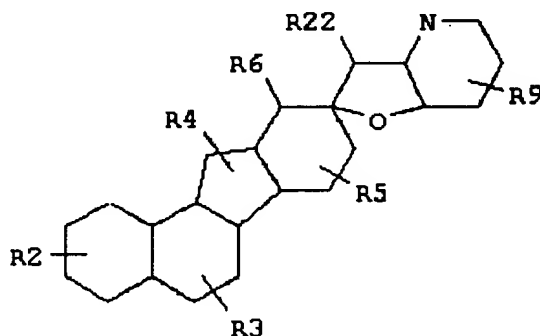
alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

and

n and m are, independently, zero, 1 or 2;

with the proviso that T, T', B and R<sub>9</sub>, taken together include at least one primary or secondary amine.

7. (Reiterated) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified steroidal alkaloid represented in the general formula (IV), or unsaturated forms thereof and/or seco-, nor- or homo- derivatives thereof:



Formula IV

wherein

R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>5</sub>, represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

R<sub>6</sub> is absent or represents halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls,

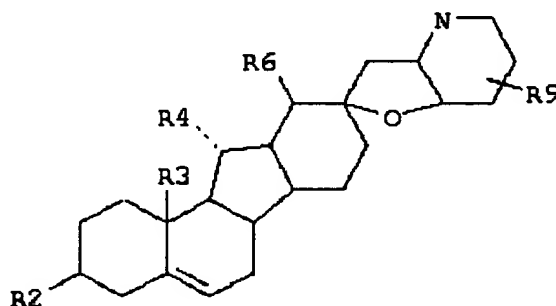
phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

$R_8$  represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

$R_9$  represents one or more substitutions to the ring A or B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ; and

$R_{22}$  is absent or represents an alkyl, an alkoxyl or  $-OH$ .

8. (Reiterated) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified steroidal alkaloid represented in the general formula (V) or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula V

wherein

$R_2$ ,  $R_3$ , and  $R_4$ , represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls,

carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

$R_6$  is absent or represents halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

$R_8$  represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

$R_9$  represents one or more substitutions to the ring A or B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ .

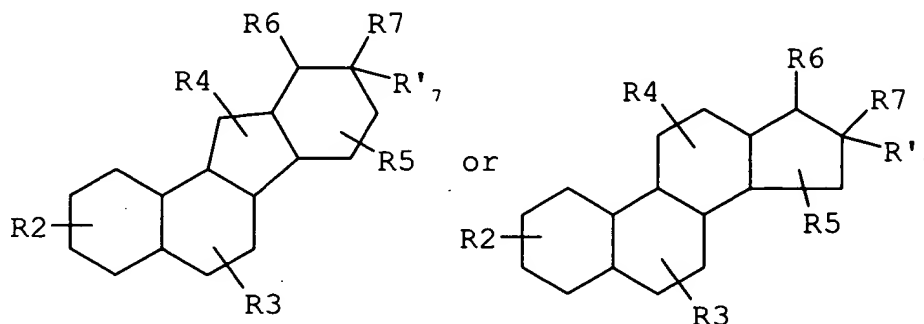
11. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not substantially interfere with the biological activity of such steroids as aldosterone, androstane, androstene, androstenedione, androsterone, cholecalciferol, cholestane, cholic acid, corticosterone, cortisol, cortisol acetate, cortisone, cortisone acetate, deoxycorticosterone, digitoxigenin, ergocalciferol, ergosterol, estradiol-17- $\alpha$ , estradiol-17- $\beta$ , estriol, estrane, estrone, hydrocortisone, lanosterol, lithocholic acid, mestranol,  $\beta$ -methasone, prednisone, pregnane, pregnenolone, progesterone, spironolactone, testosterone, triamcinolone and their derivatives.

12. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not specifically bind a nuclear hormone receptor.

13. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not specifically bind estrogen or testosterone receptors.

14. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid has no estrogenic activity at therapeutic concentrations.

15. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an  $ED_{50}$  of 1 mM or less.
16. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an  $ED_{50}$  of 1  $\mu$ M or less.
17. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an  $ED_{50}$  of 1 nM or less.
20. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid is administered as part of a therapeutic or cosmetic application.
22. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid is applied as a topical formulation.
24. (Reiterated) A pharmaceutical preparation comprising steroidal alkaloid is represented in the general formulas (I), or unsaturated forms thereof and/or seco-, nor- or homo- derivatives thereof:



Formula I

wherein, as valence and stability permit,

$R_2$ ,  $R_3$ ,  $R_4$ , and  $R_5$ , represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides,

phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ ;

$R_6$ ,  $R_7$ , and  $R'_7$ , are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl,  $=O$ ,  $=S$ , alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or  $-(CH_2)_m-R_8$ , or

$R_6$  and  $R_7$ , or  $R_7$  and  $R'_7$ , taken together form a ring or polycyclic ring, e.g., which is substituted or unsubstituted, with the proviso that at least one of  $R_6$ ,  $R_7$ , or  $R'_7$  is present and includes a primary or secondary amine;

$R_8$  represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

$m$  is an integer in the range 0 to 8 inclusive.

25. (Reiterated) The preparation of ~~Claim~~ 24, formulated for topical application.

26. (Reiterated) A process for manufacturing a medicament comprising formulating a steroid alkaloid inhibitor of a hedgehog signal transduction pathway in a pharmaceutically acceptable excipient to form a sterile medicament for preventing growth of cells having an aberrant activation hedgehog pathway.